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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,852	09/09/2003	Jeroen Demmer	11000.1070U	3215
20601	7590	01/28/2005	EXAMINER	
SPECKMAN LAW GROUP PLLC 1501 WESTERN AVE SEATTLE, WA 98101			KAUSHAL, SUMESH	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,852

Applicant(s)

DEMMER ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 10-17, drawn to isolated polynucleotide selected from group consisting of SEQ ID NO:1-12 and 25, classified in class 536, subclass 23.1.
- II. Claims 6-9, 26-27, 29 and 34, drawn to an isolated polypeptide selected from group consisting of SEQ ID NO:13-24 and 26, classified in class 530, subclass 350.
- III. Claims 18-20, drawn to method of modulating cold tolerance in an organism using a polynucleotide (as claimed), classified in class 514, subclass 44.
- IV. Claims 21-22, drawn to a method for producing a transgenic plant having altered cold tolerance using a polynucleotide (as claimed), classified in class 800, subclass 278.
- V. Claims 23-24, drawn to a method of modifying the activity of an antifreeze protein in an organism by administering dsRNA to the organism (derived from a polynucleotide as claimed), classified in class 514, subclass 44.
- VI. Claim 25, drawn to a method of cryopreserving a cell or tissue using the polypeptide (as claimed), classified in class 435, subclass 2.
- VII. Claim 28, drawn to a method of decreasing an amount of time required to dehydrate a composition using a polypeptide (as claimed), classified in class 435, subclass 2.
- VIII. Claim 30, drawn to a method for the treatment of a disorder characterized by unwanted biocrystals using a polypeptide (as claimed), classified in class 514, subclass 2.
- IX. Claim 31, drawn to a method for preserving the viability of molecular biology reagent using a polypeptide (as claimed), classified in class 435, subclass 4.

Art Unit: 1636

- X. Claims 32-33 and 35, drawn to a method of destroying unwanted tissue in a patient using a polypeptide (as claimed), classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case polynucleotides and polypeptides are structurally and functionally distinct products having different modes of operation, functions and/or effects. For example polypeptides are biologically active compounds, whereas the nucleic acid requires the modification to an expression vector and incorporation into a host cell in order to express the encoded protein. Furthermore the polypeptide can be isolated from cells expressing the native proteins, rather than by recombinant means. Thus, these inventions are distinct and are of separate use.

Inventions III-V are distinct from inventions of groups VI-X. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case method that requires the use of a polynucleotide is distinct from a method that requires the use of a polypeptide because polynucleotides and polypeptides are structurally and functionally distinct products having different modes of operation, functions and/or effects. For example polypeptides are biologically active compounds, whereas the nucleic acid requires the modification to an expression vector and incorporation into a host cell in order to express the encoded protein. Thus these inventions are distinct and are of separate uses.

Inventions III, IV and V are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case method of modulating cold tolerance by administering a polynucleotide is

distinct from a method of modifying the activity of an antifreeze protein in an organism by administering dsRNA, which is further distinct from a method of for producing transgenic plants, since each have different modes of operation, functions, or effects. For example method of gene delivery to mature organism is distinct from method of making transgenic organisms because these methods requires different material and protocols. In addition modulation of gene expression by a polynucleotide is distinct from using dsRNA, since these methods requires structurally different products having different functions. Thus these inventions are distinct and are of separate uses.

Inventions VI, VII, VIII, IX and X are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case method of cryopreserving, preserving reagents and dehydration each have different modes of operation and effects. Furthermore treatment of a disorder characterized by unwanted biocrystals have different modes of operation, functions and effects as compared to a method of destroying unwanted tissue in a patient. Thus these inventions are distinct and are of separate use, since use of one is not required for another.

In order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

With regard to Groups I, III, IV and V the independent and distinct Inventions are as follows:

- a) SEQ ID NO:1
- b) SEQ ID NO:2
- c) SEQ ID NO:3
- d) SEQ ID NO:4
- e) SEQ ID NO:5
- f) SEQ ID NO:6
- g) SEQ ID NO:7

Art Unit: 1636

- h) SEQ ID NO:8
- i) SEQ ID NO:9
- j) SEQ ID NO:10
- k) SEQ ID NO:11
- l) SEQ ID NO:12
- m) SEQ ID NO:25

With regard to Groups VI, VII, VIII, IX and X the independent and distinct Inventions are as follows:

- a) SEQ ID NO:13
- b) SEQ ID NO:14
- c) SEQ ID NO:15
- d) SEQ ID NO:16
- e) SEQ ID NO:17
- f) SEQ ID NO:18
- g) SEQ ID NO:19
- h) SEQ ID NO:20
- i) SEQ ID NO:21
- j) SEQ ID NO:22
- k) SEQ ID NO:23
- l) SEQ ID NO:24
- m) SEQ ID NO:26

With regard to Groups III the independent and distinct Inventions are as follows:

- a) Plants
- b) Mammal
- c) Insect
- d) Fungi
- e) Archaea
- f) bacteria

With regard to Groups IV the independent and distinct Inventions are as follows:

- a) Lolium
- b) Festuca
- c) Eucalyptus

With regard to the different Inventions above, the burden of search exists because a different search is required for each separate invention. Furthermore these inventions

have different modes of operation, functions and effects, which need to be searched and reviewed separately. Since the review of this information would be different for each invention it would be burdensome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

Art Unit: 1636

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571-272-0547. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Sumesh Kaushal
Examiner GAU 1636



SUMESH KAUSHAL
PATENT EXAMINER